

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
\_\_\_\_\_ )

MDL No. 2419  
Dkt. No 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO: )

All Cases )  
\_\_\_\_\_ )

**The Tennessee Clinic and Health Care Provider Defendants’  
Response to the PSC’s Memorandum in Support of  
Proposals for Plaintiffs’ Profile Form and Records Releases**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively “the Tennessee Defendants”) file this Response to the PSC’s Memorandum in Support of Proposals for Plaintiffs’ Profile Form and Records Releases [Dkt. 810].

**Introduction**

The Tennessee Defendants respectfully request that the Court adopt their Plaintiff Profile Form attached as Exhibit A to their previously-filed Memorandum in Support of their Plaintiff Profile Form [Dkt. 807, Ex. A].

It represents a middle ground between the proposals of the Plaintiffs’ Steering Committee (“PSC”) and the Saint Thomas Entities<sup>1</sup>, and it reasonably seeks information necessary to select the initial pool of bellwether trial candidates, while at the same time balancing the burden on individual Plaintiffs completing the form.

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<sup>1</sup> The “Saint Thomas Entities” include Saint Thomas West Hospital f/k/a Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Health.

On January 24, 2014, the Tennessee Defendants and the Saint Thomas Entities filed their proposed Plaintiff Profile Forms.<sup>2</sup> On January 27, 2014, the PSC filed its proposed Plaintiff Profile Form. The parties generally agree on the content of much of the form, but material differences remain in the various competing proposals. The Court ordered the parties to respond to each other's proposals by January 31, 2014. The Tennessee Defendants file this response.

### **Law and Argument**

As discussed at length in their previously-filed brief, there are two operative questions in deciding whether to include a given question in the Plaintiff Profile Form:

1. Is the information sought by the question relevant to any of the primary variables at issue in this case, including:
  - i. Type of injury (e.g., death, stroke, fungal meningitis, emotional injury only, etc.)<sup>3</sup>;
  - ii. Whether the Plaintiff received contaminated MPA<sup>4</sup>;
  - iii. State where the injury occurred (including clinic where the MPA was administered);
  - iv. Underlying health of the individual (e.g., personal medical history, family medical history, identification of treating providers, etc.)<sup>5</sup>; and

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<sup>2</sup> [Dkts. 807, 808].

<sup>3</sup> The injury spectrum for these cases spans from “fear of illness” claims with no physical injury to death. The parties will have to, based on the profile forms, determine what injuries are most representative. The parties will also need to consider whether an individual case has unique causation issues that disqualify it as a bellwether trial candidate (e.g., an underlying illness that caused the problems or made them worse).

<sup>4</sup> The majority of the Plaintiffs complain of injuries arising from their receipt of NECC MPA. Those Plaintiffs who claim injuries arising from other medications are likely not representative of the overall pool of Plaintiffs.

<sup>5</sup> Contrary to the PSC's assertion in its Response [Dkt. 835], the causation issues in this case are far from simple. More than 13,000 people were exposed to contaminated MPA from NECC, but only a small fraction, 751, became ill. Marion Kainer, *et al.*, *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N. ENGL. J. MED. 2013;369:1598, 1598 (Dec. 12, 2012). No hypothesis explaining this relatively low incidence of infection has gained general acceptance among medical experts. A patient's underlying health condition could prove key to explaining this discrepancy. Until this question is resolved, causation is far from clear-cut.

- v. Nature and extent of damages (e.g., employment information, treatment for injury related to medication, consortium claim information, etc.)?
2. If the information is relevant to any of these variables, how much of the information is necessary for selection of the initial bellwether pool?

In answering the second question, in order to further the goal of the bellwether selection process, the Court should focus on how much information is necessary to determine whether an individual Plaintiff is representative of the Plaintiffs as a group.<sup>6</sup>

Applying these principals to the areas of dispute, the Tennessee Defendants' proposed Plaintiff Profile Form seeks only information necessary to select the initial bellwether pool, without unduly burdening the Plaintiffs.

Respectfully, it is the appropriate compromise between the proposals of the PSC and the Saint Thomas Entities.<sup>7</sup>

### **I. Striking a Balance Between Competing Proposals**

Three proposed profile forms are currently before the Court:

- (1) the PSC's proposed profile form,
- (2) the Tennessee Defendants' proposed profile form, and
- (3) the Saint Thomas Entities' proposed profile form.

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<sup>6</sup> *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997) (noting that bellwether trials must have a "core element of representativeness"); Eldon E. Fallon, *et al.*, *Bellwether Trials in Multidistrict Litigation*, 82 TULANE LAW REV. 2323, 2343 (2008) (emphasizing the importance of ensuring the representativeness of the cases chosen as bellwethers); MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 ("[T]o produce reliable information about other mass tort cases, the specific Plaintiffs and their claims should be representative of the range of cases.").

<sup>7</sup> The information sought by the questions the Tennessee Defendants agreed to remove from their Plaintiff Profile Form is certainly *discoverable*, and they have only agreed to remove those questions with the understanding that further discovery will occur in the individual case discovery phase.

Attached as Exhibit A is a chart that succinctly demonstrates that the Tennessee Defendants' proposal strikes a fair and reasonable balance between the PSC's proposed form and the Saint Thomas Entities' proposed form. The chart provides a side-by-side-by-side comparison of the primary areas of dispute and the information sought by each proposal with regard to the disputed questions.

The Tennessee Defendants' proposed form strikes a middle ground on many of the issues.

The Tennessee Defendants endeavored to make their questions simpler and, thus, easier for the Plaintiffs to answer.<sup>8</sup> Also, the Tennessee Defendants' proposed 14-page<sup>9</sup> form splits the difference between the PSC's proposed ten-page form and the Saint Thomas Entities' proposed 18- page form.

The Tennessee Defendants' form also serves as a middle ground for the substantive content provided by the other two proposed forms, primarily in that the Tennessee Defendants' form seeks less detailed and less specific information to minimize the burden on the Plaintiffs in the hopes of making the form palatable to the PSC.<sup>10</sup>

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<sup>8</sup> For example, the Tennessee Defendants changed some of the questions requiring the Plaintiffs to write out and/or explain answers so that the Plaintiffs only need to check a box for "Yes," "No," or "Don't know." (Compare question 26 of the Tennessee Defendants' proposed form *with* questions 29 and 30 of the Saint Thomas Entities' proposed form.)

<sup>9</sup> The Tennessee Defendants added some spacing to their proposed form to improve formatting which adds at least a page to it. When formatted like the other two proposed profile forms, the Tennessee Defendants' proposed profile form is 14 pages long. See, e.g., pages 6, 13 of the Tennessee Defendants' proposed profile form.

<sup>10</sup> The Tennessee Defendants in no way believe that the form submitted by the Saint Thomas Entities is inappropriate or incompatible with what has been done in other MDLs. However, in an attempt to file a proposal fair to all parties, the Tennessee Defendants have diverged from the Saint Thomas Entities on some specific categories of information, mostly attempting to craft the questions or requests in a less burdensome and easier to answer format.

The PSC's form departs more significantly from the Tennessee Defendants' proposal in that it provides less specific and less detailed information on many topics, AND it provides zero information on many crucial topics.

During the meet and confer process, the PSC raised concerns regarding the amount of detail required by several questions, but the PSC's solution, as embodied in its proposed profile form, was to remove the questions entirely, rather than alter them so they seek less detailed information.<sup>11</sup> The Tennessee Defendants chose the latter, more reasonable route, in their attempt to compromise on specific issues and proffer to the Court a satisfactory resolution balancing the interests of all involved.

## **II. Specific Areas of Dispute**

To the extent the Court would like to consider the roughly 15-20 specific areas of disagreement between the PSC and the Tennessee Defendants' proposals, the Tennessee Defendants identify below the specific areas of disagreement and explain why the information is necessary at this particular stage of the MDL.

### **A. Timeframe**

A major dispute between the parties is the time period covered by the profile form. This point is discussed at length in the Tennessee Defendants' previously-filed Memorandum in Support of their Proposed Plaintiff Profile Form [Dkt. 810].

The Tennessee Defendants maintain that ten years is the reasonable and appropriate timeframe for responsive information, for three simple reasons:

1. Ten years of data is necessary to obtain a full picture of, among other things, a Plaintiff's health and employment history.

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<sup>11</sup> *E.g.*, questions 42 and 43 of the Tennessee Defendants' proposed profile form.

2. It is much more efficient to have the Plaintiffs provide ten years of information now, rather than going back later and asking the Plaintiffs to piece together the missing years during the individual discovery phase.
3. The standard timeframe used in most MDLs is ten years.

Accordingly, the Court should adopt a profile form that requires the Plaintiffs to provide ten years of information.

**B. Basic Demographic Information**

The PSC removed several questions requiring the Plaintiffs to provide very basic demographic information, including gender, last four digits of Social Security number, date of birth, place of birth, and driver's license number.<sup>12</sup> During the meet and confer process, the PSC never expressed any intent to remove most of this information from the profile form, with the exception of driver's license number and *full* Social Security number. The PSC indicated that the last four digits of the Plaintiffs' Social Security numbers would be acceptable. It is unclear why the PSC removed the other information.

This information is intended to assist the Defendants in locating and obtaining the Plaintiffs' records and doing other basic investigation of the Plaintiffs. Most records are kept using some combination of date of birth, Social Security number, and/or driver's license number. Notably, this information is not at all burdensome for the Plaintiffs to provide, as it can be provided, mostly, from memory, with no counsel needed.

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<sup>12</sup> Questions 16-19 of the Tennessee Defendants' proposed profile form.

### **C. Other Lawsuits Filed**

The PSC removed the question requiring the Plaintiffs to identify suits filed for alleged injuries resulting from their receipt of NECC medication.<sup>13</sup> This question is obviously relevant to the bellwether selection process because a Plaintiff with multiple suits pending could create procedural issues that hinder the process.<sup>14</sup> Additionally, this basic information will allow counsel receiving these forms to efficiently catalogue the information and attribute it to the appropriate individual lawsuit.

The PSC also removed the question requiring the Plaintiffs to identify previous personal injury suits.<sup>15</sup> Certainly, previous personal injuries are relevant to a Plaintiff's damages and underlying health condition.

### **D. Illnesses Allegedly Caused by NECC MPA**

The PSC removed several questions requiring the Plaintiffs to provide substantive information regarding the illnesses they claim were caused by the NECC MPA, including:

- (1) What symptoms they claim to have experienced due to their receipt of NECC MPA and when they began experiencing those symptoms<sup>16</sup>;
- (2) Whether they were ever tested for fungal infection and the results of testing<sup>17</sup>;
- (3) Whether they continue to suffer from the injury they claim was caused by the NECC MPA<sup>18</sup>;

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<sup>13</sup> Question 4 of the Tennessee Defendants' proposed profile form.

<sup>14</sup> For example, at least one Plaintiff filed suits against Saint Thomas Outpatient Neurosurgical Center in both the MDL and the federal district court for the Middle District of Tennessee. Both suits are now pending in the MDL. *Patel v. Ameridose, et al.*, Case No. 1:13-cv-12061-FDS; *Patel, et al., v. Ameridose, et al.*, Case No. 1:14-cv-10163-FDS.

<sup>15</sup> Question 14 of the Tennessee Defendants' proposed profile form.

<sup>16</sup> Question 31 of the Tennessee Defendants' proposed profile form.

<sup>17</sup> Question 32 of the Tennessee Defendants' proposed profile form.

<sup>18</sup> Question 33 of the Tennessee Defendants' proposed profile form.

- (4) Whether they were actually diagnosed by a physician with the illness they claim was caused by the NECC MPA<sup>19</sup>;
- (5) Whether any health care provider told them their illness was caused by the NECC MPA<sup>20</sup>; and
- (6) Whether they claim their receipt of NECC MPA aggravated a preexisting condition<sup>21</sup>.

There can be no meaningful dispute that these items are relevant to damages. The question is only whether this information is necessary for selection of the initial bellwether pool.

The onset of symptoms is important because a Plaintiff who began experiencing symptoms in August or September 2012 would have experienced a very different course of treatment than a Plaintiff who began experiencing symptoms in December 2012. Additionally, the type of symptom is an important consideration because a Plaintiff who experienced only a headache (as opposed to a more serious onset) may or may not be a representative Plaintiff.

Obviously, whether a Plaintiff was actually tested for and diagnosed by a physician as having a fungal infection is important for bellwether selection. Some Plaintiffs claim they suffered from fungal infections but were never actually diagnosed or treated. Similarly, whether a health care provider told them their alleged illness was caused by the NECC MPA is also relevant. Some Plaintiffs claim they suffered strokes or stroke-like symptoms due to their receipt of NECC MPA, but strokes have many other potential causes. It is important to determine whether unique causation disputes exist in selecting representative cases.

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<sup>19</sup> Question 34 of the Tennessee Defendants' proposed profile form.

<sup>20</sup> Question 35 of the Tennessee Defendants' proposed profile form.

<sup>21</sup> Question 36 of the Tennessee Defendants' proposed profile form.



Along those same lines, Plaintiffs who claim their illness aggravated a preexisting condition may not be representative of the Plaintiffs as a group.

Finally, a Plaintiff who is still being treated for fungal infection is probably an outlier because he or she will present additional difficulties in determining damages.

Importantly, again, this information can be provided from memory by the Plaintiff. Thus, the burden is minimal.

#### **E. Communications regarding NECC Products**

The PSC removed the question and two document requests requiring the Plaintiffs to identify and/or produce any communications with a health care provider related to NECC's products.<sup>22</sup>

This question is directly relevant to two of the Plaintiffs' causes of action: (1) the alleged failure to inform the Plaintiffs that a compounded product was being used for their injection<sup>23</sup>, and (2) the alleged failure to promptly notify the Plaintiffs of their receipt of potentially-contaminated medication after the Tennessee Department of Health initially discovered the outbreak<sup>24</sup>. Whether a Plaintiff did or did not receive such a warning or prompt notification is crucial in determining whether they are representative Plaintiffs with respect to these two claims, as these facts are at the crux of the claim.

#### **F. Loss of Income**

The PSC's form does not require the Plaintiffs to provide any basis for their claims for loss of income, only the amount.<sup>25</sup>

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<sup>22</sup> Question 38 of the Tennessee Defendants' proposed profile form; document requests 3 and 4 of the Tennessee Defendants' proposed profile form.

<sup>23</sup> Master Compl. Count VIII.

<sup>24</sup> Master Compl. ¶ 234(v).

<sup>25</sup> Question 7 of the Tennessee Defendants' proposed profile form; question 4 of the PSC's proposed profile form.

The amount of lost income is obviously relevant to determining whether a Plaintiff is representative. However, the amount alone, without some basis, is inadequate to allow the Defendants to evaluate whether the Plaintiff is appropriate for the initial bellwether pool.

It would be terribly inefficient for all parties to begin discovery of the initial bellwether pool only to discover that half the Plaintiffs in the pool inflated their claims for loss of income and were not actually representative Plaintiffs. A simple explanation of, for example, “Six months of lost wages at \$4,000/month” is not burdensome to provide and potentially averts unnecessary selection into (or elimination from) the bellwether trial candidate pool.

**G. Loss of Consortium**

The PSC removed the question requiring the Plaintiffs to state whether they filed a loss of consortium claim and identify the spouse or family member(s) filing the claim.<sup>26</sup>

The Tennessee Defendants cannot conceive of a colorable basis for excluding this question. The parties need to know whether the initial bellwether pool should include a suit with a claim for loss of consortium.

Similarly, the PSC’s form does not require the Plaintiffs to disclose their spouse’s date of birth or occupation. Both points are directly relevant to the value of the loss of consortium claim. An elderly spouse with retirement income will have a very different loss of consortium claim than a young, stay-at-home parent.

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<sup>26</sup> Questions 23 and 25 of the Tennessee Defendants’ proposed profile form; question 10 of the PSC’s proposed profile form.

## H. Personal Medical History

The Tennessee Defendants' profile form asks the Plaintiffs whether a health care provider has diagnosed them with various common health conditions (e.g., hypertension, high cholesterol, heart disease, *etc.*).<sup>27</sup> The Plaintiffs removed about half of those health conditions from the list<sup>28</sup> and also removed several "catchalls"<sup>29 30</sup>.

The health conditions are relevant to a Plaintiff's life expectancy, baseline health condition, and/or unique causation issues (*i.e.*, previous diagnosis of spinal abscess as compared to diagnosis of abscess following injection with NECC MPA). The catchalls were included because most of the Plaintiffs are not medical professionals and may not know (or may have forgotten) the name of a specific disease they suffer from. The catchalls will also help weed out any Plaintiffs with rare diseases not specifically identified in the list.

## I. Family Medical History

The PSC's form does not provide any information on family medical history.<sup>31</sup>

This information is important in determining the extent of a Plaintiff's damages as it impacts life expectancy, and the information will help identify cases with unique causation issues. A Plaintiff who suffered a stroke allegedly resulting from their receipt of NECC MPA who has a family history of stroke may have unique causation issues.

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<sup>27</sup> Question 44 of the Tennessee Defendants' proposed profile form.

<sup>28</sup> The PSC removed high cholesterol, hypertension, neuropathy, thyroid disorder, arthritis, chronic pain, stroke, liver disease, metabolic syndrome, enlarged prostate, osteomyelitis, spinal abscess, and depression.

<sup>29</sup> The PSC removed the following catchalls: "or other heart disease", "or other respiratory disease", and "or other vascular disease".

<sup>30</sup> Question 23 of the PSC's proposed profile form.

<sup>31</sup> Question 26 of the Tennessee Defendants' proposed profile form.

Similarly, a Plaintiff with a family history of autoimmune disorders may have an undiagnosed disorder that would make them an unrepresentative Plaintiff. The PSC affirmatively alleged in the Master Complaint that fungal meningitis affects individuals with autoimmune disorders differently.<sup>32</sup> To then eliminate it from the process by which the parties select representative cases is illogical.

#### **J. Substance Abuse**

The PSC removed the questions requiring the Plaintiffs to identify alcohol or illicit drug use.<sup>33</sup> Both are relevant to damages as they affect life expectancy. An alcoholic or drug addict has a shorter life expectancy and is likely a non-representative Plaintiff.<sup>34</sup>

#### **K. Identification of Treating Health Care Providers**

The PSC's form only requires the Plaintiffs to identify physicians from whom they received treatment, omitting nurse practitioners, therapists, psychiatrists, *etc.*, and it does not require the Plaintiffs to identify the diagnosis or treatment received.<sup>35</sup>

One of the purposes of this question is to identify treating health care providers so the Defendants can obtain records from them. Obviously, the Defendants are entitled to records from nurse practitioners as well as physicians. The information regarding diagnosis and treatment will enable the Defendants to determine whether they need to obtain the medical records from a given health care provider at all.<sup>36</sup>

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<sup>32</sup> Master Compl. ¶¶ 57, 59 and 156.

<sup>33</sup> Questions 42 and 43 of the Tennessee Defendants' proposed profile form.

<sup>34</sup> The Tennessee Defendants have altered the original inquiry to make it the least intrusive possible while still identifying those non-representative alcohol or drug abusers.

<sup>35</sup> Question 47 of the Tennessee Defendants' proposed profile form; question 26 of the PSC's proposed profile form.

<sup>36</sup> For example, medical records from laser eye surgery are probably not relevant to the case at bar.

## **L. Medication Use**

The PSC removed the question requiring the Plaintiffs to identify whether they had ever taken nine specific types of medications.<sup>37</sup>

Most of the medications treat pain.<sup>38</sup> Use of those medications helps the Defendants evaluate a Plaintiff's damages because the types of pain relievers taken by the Plaintiff indicate the severity of the Plaintiff's pain.

Identification of the Plaintiffs who used the other medications in the list – disease modifying medications, fungal medications, steroids, and other injectable products – will help weed out unique causation issues.

Disease modifying agents and fungal medications may have affected a Plaintiff's ability to fight off fungal infection.

Likewise, steroids can affect immune response, as the PSC correctly pointed out in the Master Complaint.<sup>39</sup> If a Plaintiff were taking another steroid when they received the NECC MPA, the steroid may have affected their immune response to the fungus. Given that the medication at issue was administered by injection, the use of other injectable medication could clearly have some impact on a Plaintiff's illness, creating unique causation issues.

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<sup>37</sup> Question 46 of the Tennessee Defendants' proposed profile form; question 26 of the PSC's proposed profile form.

<sup>38</sup> The list includes: narcotic pain relievers, analgesics, non-steroid anti-inflammatory agents, muscle relaxers, and over-the-counter (non-prescribed) pain relievers.

<sup>39</sup> Master Compl. ¶ 156.

### **M. Disability and Workers' Compensation**

The PSC's form does *not* require the Plaintiffs to identify *applications* for disability or workers' compensation, only *awards*, and it does *not* require the Plaintiffs to disclose the time period of the awards.<sup>40 41</sup>

Applications for disability or workers' compensation may help identify previous health problems that may have resurfaced following a Plaintiff's receipt of NECC MPA. Such health problems are relevant to damages and may create unique causation issues.

The length of a Plaintiff's disability award is a simple method of evaluating the severity of the disability. A ten-year period of disability is materially different from a ten-month period of disability, with the length of the disability potentially affecting whether a Plaintiff is representative.

### **N. Lienholders**

The PSC's form does not require a Plaintiff to provide the address of entities with liens against the Plaintiff's recovery, including health insurers.<sup>42</sup> The Defendants need the address so they know where to send the release for insurance records the Plaintiffs have agreed to execute.

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<sup>40</sup> Questions 9-13 of the Tennessee Defendants' proposed profile form; questions 5 and 6 of the PSC's proposed profile form.

<sup>41</sup> The PSC maintained throughout the meet and confer process that the questions regarding disability and workers' compensation *applications* should be removed from the form. But, the PSC's proposed form seems to provide information regarding applications. Because the Tennessee Defendants may be misinterpreting the PSC's proposal, they have explained the need for disability and workers' compensation applications.

<sup>42</sup> Question 15 of the Tennessee Defendants' proposed profile form; question 7 of the PSC's proposed profile form.

**O. Mental Health Treatment**

The PSC's form does not require the Plaintiffs to provide dates of treatment for mental health treatment or the treatment provider's address.<sup>43</sup>

The dates of treatment are necessary to evaluate the extent of the emotional damages and to determine whether treatment is ongoing. Both are relevant to whether a Plaintiff is representative. The address is necessary to obtain the records using the records release the Plaintiffs have agreed to execute.

**P. Autopsy Report**

The PSC's form omits the document request for a deceased Plaintiff's autopsy report.<sup>44</sup> The autopsy report is vital for determining whether a deceased Plaintiff is representative because a Plaintiff whose cause of death was determined to be something other than fungal meningitis will likely present unique causation issues.

**Conclusion**

For the reasons set forth in this Response and their previously-filed Memorandum in Support of their Proposed Plaintiff Profile Form [Dkt. 807], the Tennessee Defendants respectfully request that the Court adopt the Tennessee Defendants' proposed Plaintiff Profile Form [Dkt. 807, Ex. A].

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<sup>43</sup> Question 37 of the Tennessee Defendants' proposed profile form; questions 18 and 19 of the PSC's proposed profile form.

<sup>44</sup> Document request 2 of the Tennessee Defendants' proposed profile form.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 31st day of January, 2014.

/s/ Chris J. Tardio

**Chris J. Tardio**